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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,572	03/22/2001	Romulus Kimbro Brazzell	OP/4-31363A	4539

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EXAMINER	
THOMPSON, KATHRYN L	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/814,572	BRAZZELL, ROMULUS KIMBRO	
	Examiner	Art Unit	
	Kathryn L Thompson	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,18 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-7*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 16 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10. Applicant's election with traverse of Group I, Claims 1-15 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that "the dual criteria of the statute must be met, that is, the application must contain two or more inventions which are both (1) "independent" and (2) "distinct" from one another." Applicant also traverses that there is no serious burden on the examiner.

This is not found persuasive because Applicant's arguments are directed towards 35 USC 121, which states what is proper for a SPECIES election. Examiner did not place a species requirement on the instant application. The criteria needed for a group restriction is different than the criteria needed for a species election. Examiner maintains, as stated in the Restriction requirement mailed in October, 2003, that what needs to be proven in order for the restriction requirement to be proper, according to the MPEP, 806.05 (e), is that, "The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process.

(MPEP § 806.05(e))." In this case the process as claimed can be practiced by another materially different apparatus such as a catheter, needle, transdermal drug delivery device, or a pill. The requirement is still deemed proper and is therefore made FINAL.

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Clark (US 6,297,228). Clark discloses a method for treating neovasculature in a subject comprising administering an effective amount of an anti-angiogenic agent to the subject, administering an effective amount of a photosensitive agent to the subject, and irradiating the neovasculature with light having a wavelength absorbable by the photosensitive agent (Column 2, Lines 29-31), wherein the anti-angiogenic agent and the photosensitive agent are administered simultaneously (Column 6, Lines 5-8), wherein the subject is suffering from choroidal neovascularization, and wherein the subject is suffering from retinal neovascularization (Column 4, Lines 23-41).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4, 6, 7, 8, and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Dimitroff et al ("Anti-angiogenic activity of selected receptor tyrosine kinase inhibitors, PD166285 and PD173074:Implications for combination treatment with photodynamic therapy."). Dimitroff et al discloses a method for treating neovasculature in a subject comprising administering an effective amount of an anti-angiogenic agent to the subject, administering an effective amount of a photosensitive agent to the subject, and irradiating the neovasculature with light having a wavelength absorbable by the photosensitive agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 4, 5, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark. Clark teaches all of the claimed limitations except administering the anti-angiogenic agent between about 0-4 weeks before administration of the photosensitive agent, administering the anti-angiogenic agent between about 0-4 weeks after administration of the photosensitive agent, and administering the anti-angiogenic agent between about 0-4 weeks before administration of the photosensitive agent and between about 0-4 weeks after administration of the photosensitive agent. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to choose between about 0 to about 4 weeks as the time interval because Applicant has not disclosed that using between about 0 to about 4 weeks as the time interval provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the time interval taught by Clark or the claimed time interval because both time intervals perform the same function. Therefore, it would have been an obvious matter of design choice to modify Clark to obtain the invention as specified in Claims 2, 4, and 5.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of Brazzell et al (US 6,271,233). Clark teaches all of the claimed limitations except an anti-angiogenic selected from the group consisting of inhibitors of protein kinase C, antagonists of growth hormone, antagonists of IGF-1, antagonists of vascular endothelial growth factor, inhibitors of cyclooxygenase II, antagonists of angiotensin II, antagonists of NF-kappa B, and phospholipase A2 antagonists, N-benzoyl-staurosporine, CGP 79787, and octreotide. Brazzell et al teaches an anti-angiogenic selected from the group consisting of inhibitors of protein kinase C, antagonists of growth hormone, antagonists of IGF-1, antagonists of vascular endothelial growth factor, inhibitors of cyclooxygenase II, antagonists of angiotensin II, antagonists of NF-kappa B, and phospholipase A2 antagonists, N-benzoyl-staurosporine, CGP 79787, and octreotide. It would have been obvious to one with ordinary skill in the art to use the teachings of Brazzell et al to modify the invention of Clark and use anti-angiogenic agents as claimed by Brazzell et al since those of Brazzell et al are notoriously well known in the art as effective anti-angiogenic agents.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of Brazzell et al, further in view of Brazzell et al (6,214,819). Clark teach all of the claimed limitations except wherein the anti-angiogenic agent is N-benzoyl-staurosporine. Brazzell et al ('819) discloses wherein the anti-angiogenic agent is N-benzoyl-staurosporine. It would have been obvious to one with ordinary skill in the art to use the teachings of Brazzell et al ('819) to modify the invention of Clark and Brazzell

et al and use the anti-angiogenic agent N-benzoyl-staurosporine since it is notoriously well known in the art as an effective anti-angiogenic agent.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark in view of Richter et al (5,770,619). Clark discloses all of the claimed limitations except wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A. Richter et al discloses wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A. It would have been obvious to one with ordinary skill in the art to use the teachings of Richter et al to modify the invention of Clark wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A since these are notoriously well known in the art as effective photosensitive agents.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dimitroff et al in view of Brazzell et al (US 6,271233). Dimitroff et al teach all of the claimed limitations except an anti-angiogenic selected from the group consisting N-benzoyl-staurosporine, CGP 79787, and octreotide. It would have been obvious to one with ordinary skill in the art to use the teachings of Brazzell et al to modify the invention of Dimitroff et al and use anti-angiogenic agents as claimed by Brazzell et al since those of Brazzell et al are notoriously well known in the art as effective anti-angiogenic agents.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dimitroff et al in view of Brazzell et al ('233), further in view of Brazzell et al ('819). Dimitroff et al

and Brazzell et al ('233) teach all of the claimed limitations except wherein the anti-angiogenic agent is N-benzoyl-staurosporine. Brazzell et al ('819) discloses wherein the anti-angiogenic agent is N-benzoyl-staurosporine. It would have been obvious to one with ordinary skill in the art to use the teachings of Brazzell et al ('819) to modify the invention of Dimitroff et al and Brazzell et al ('233) and use the anti-angiogenic agent N-benzoyl-staurosporine since it is notoriously well known in the art as an effective anti-angiogenic agent.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dimitroff et al in ivew of Richter et al (US 5,770,619). Dimitroff et al disclose all of the claimed limitations except wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A. Richter et al discloses wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A. It would have been obvious to one with ordinary skill in the art to use the teachings of Richter et al to modify the invention of Dimitroff et al wherein the photosensitive agent is selected from the group consisting of porphyrin and a purpurin, and a benzoporphyrin derivative monacid ring A since these are notoriously well known in the art as effective photosensitive agents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-

305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KLT

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